UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,025	06/30/2003	Hirokazu Ohbayashi	239546US0CONT	8296

22850 7590 01/04/2006

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,025	OHBAYASHI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *12/20/05* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the telephonic interview, applicant preliminary amendments in canceling claims 1-26, and adding new claims 27-46 have been entered on 6/30/2005, therefore the previous Office Action mailed on 10/4/2005 is withdrawn. A new rejection on claims 27-46 is accordingly set forth in this Office Action.

Specification

1. The abstract of the disclosure is objected to because legal phraseology such as "at least one of said two or more" is used. (See line 6) Correction is required. See MPEP § 608.01(b).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 27-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 16 and 24 of U.S. Patent No. 6,613,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because

The US Patent 6,613,564 directs to *an carrier-enzyme-protein complex* comprising (1) a carrier (2) enzyme conjugates to the carrier (3) protein bind to the enzyme and said protein is not directly conjugated to said carrier, whereas the instant applicant directs to ***a product comprising*** *an carrier-enzyme-protein complex* comprising all the features, including (1)-(3) as recited in the 6,613,564 patent. The patent is for *an carrier-enzyme-protein complex,* the application is for a product comprising *an carrier-enzyme-protein complex,* Although claims are not identical, they are not patentably distinct from each other.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 39, this method of making a product lacks active step(s). There is no step of making such product. Applicant merely recites structures, e.g. carrier, enzyme or protein. Applicant needs to specify each step for making the claimed product.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 27-35, 36, 39-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohannon et al. (US 5763158).

Bohannon et al. teach a method for simultaneously testing a sample for the presence of multiple target molecules. Bohannon et al. teach use of a complex comprises a carrier, an enzyme conjugated to the carrier, and a protein with specific binding potency to other substance(s), where the protein is conjugated to the enzyme but not directly conjugated to the carrier (See Figure 1).

With respect to claim 28-29, 41-44, Bohannon et al. teach that the method can be used to detect target molecules of interest for better efficiency for immunoassay, such as enzyme immunoassay or immunohistostaining (See Abstract; Figure 2-4; Col. 1 to Col. 2).

With respect to claim 30-31, 45-46, Bohannon et al. teach the carriers can be of microplates, glass, plastic strips or nitrocellulose particle (Col. 5, line 1-10).

With respect to claims 33-35, Bohannon et al. teach that the protein with specific binding potency is a polyclonal antibody or monoclonal antibody (See Figure 1-2; claim 4).

With respect to claim 32 and 39, Bohannon et al. teach isolating or recovering the carrier-enzyme-protein complex for determining the activity of the complex for screening antibodies (Col. 10, line 15-25).

With respect to claim 36, the target molecules include virus microorganism which inherently contain sugar chain on the surface for the recognition of the protein (See claim 28-29).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohannon et al. in view of Chichibu et al. (US 5019498).

Bohannon et al. reference has been discussed for detecting various target molecules but does not explicitly teach using protein specific for hyaluronic acid.

Chichibu et al. teach using hyaluronic acid specific binding protein to detect hyaluronic acid because hyaluronic acid is a marker for inflammatory disease, such as rheumatism (See Abstract).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bohannon et al. with the hyaluronic binding protein to detect hyaluronic acid molecules in a sample as taught by Chichibu et al. because Bohannon et al. already disclose a general immunoassay by using the complex and detecting a specific target molecule merely involves routine skill in the art.

8. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bohannon et al. in view of McClintock et al. (US 5833924)

Bohannon et al. reference has been discussed for detecting various target molecules but does not explicitly teach using protein specific for biotin.

McClintock et al. teach using protein, e.g. avidin to bind to the biotin conjugated analyte to increase efficiency (Col. 7, line 38-42).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bohannon et al. with the protein, such as avidin to bind to the biotin analyte to increase detection efficiency as taught by McClintock et al. since it is well known and well practiced in the art by using the binding relationship of biotin-avidin to increase detection/or isolation efficiency.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

December 20, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/22/05